UNITED STATES DISTRICT COURT
DISTRICT OF PUERTO RICO

MUNICIPALITY OF GUAYAMA, PUERTO RICO Plaintiff, v. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO- MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and McKESSON CORPORATION. Defendants.	)	CIVIL ACTION NO. _____ COMPLAINT JURY TRIAL DEMANDED

Plaintiff, the MUNICIPALITY OF GUAYAMA, PUERTO RICO ("Plaintiff"), brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA,

Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioid.[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

3. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.
[2] See Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain— Misconceptions and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016).
[3] See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal, state and Commonwealth law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. PARTIES

A. PLAINTIFF

6. Plaintiff, the Municipality of Guayama, is a governmental entity that was formed as a municipality within the Commonwealth of Puerto Rico in accordance with the laws of the Commonwealth of Puerto Rico. Plaintiff is authorized to bring the causes of action brought herein.

7. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

8. The distribution and diversion of opioids into Puerto Rico ("the Commonwealth"), and into the municipality and surrounding areas (collectively, "Plaintiff's community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

9. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief.

Categories of past and continuing sustained damages include, *inter alia*,:

a. costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

b. costs for providing treatment, counseling, and rehabilitation services;

c. costs for providing treatment of infants born with opioid-related medical conditions;

d. costs associated with law enforcement and public safety relating to the opioid epidemic;

e. the costs of treating babies born addicted and diagnosed with Neonatal Abstinence Syndrome, and

f. and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

10. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

11. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. DEFENDANTS

i. **Manufacturer Defendants**

12. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty prevent diversion and report suspicious orders.

13. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware, PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). PURDUE PHARMA L.P. is licensed by the Puerto Rico Department of Health to operate as a drug manufacturer and distributor. THE PURDUE FREDERICK COMPANY is registered with the Puerto Rico Secretary of State to do business in Puerto Rico.

14. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

15. CEPHALON INC. is a Delaware corporation with its principal place of business in Frazer, Chester County, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. CEPHALON, INC. is licensed by the Puerto Rico

Department of Health to manufacture, label/repackage, and/or distribute prescription drugs and controlled substances at facilities in Guayama, Puerto Rico. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Montgomery County, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. Teva USA is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances at its facilities in Guayama, Puerto Rico. Teva USA is a wholly owned subsidiary of Teva Ltd. Teva USA acquired Cephalon in October 2011.

16. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[4] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[6]

17. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell

[4] Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf
[5] Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf
[6] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html

Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

18. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[8] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business

[7] E.g., ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left)
[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2 012.pdf

in New Brunswick, New Jersey. JANSSEN PHARMACEUTICALS, INC. is licensed by the Puerto Rico Department of Health is licensed to distribute prescription drugs and controlled substances by the Puerto Rico Department of Health at its facilities in Guayama, Puerto Rico. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. NORAMCO, Inc. is licensed by the Puerto Rico Department of Health as a manufacturer or repackager/labeler of prescription drugs and controlled substances. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

20. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Chester County, Pennsylvania. ENDO PHARMACEUTICALS

INC. is a wholly owned subsidiary of Endo Health Solutions Inc., is a Delaware corporation with its principal place of business in Malvern, Chester County, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. ENDO PHARMACEUTICALS INC. is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances at its facility in Guayama, Puerto Rico. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

22. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

23. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, is registered with the Puerto Rico Secretary of State to do business in Puerto Rico, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of

business in New Jersey, is registered with the Puerto Rico Secretary of State to do business in Puerto Rico, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA, INC. is licensed by the Puerto Rico Department of Health as a distributor of prescription drugs and controlled substances. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is licensed by the Puerto Rico Department of Health as a manufacturer, labeler, or repackager of prescription drugs and controlled substances. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

24. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

25. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien pllc (formerly known as Tyco Healthcare). Mallinckrodt, plc

and Mallinckrodt, LLC are referred to as "Mallinckrodt."

26. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names "M," "roxies/roxys" or "blues"). In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

ii. **Distributor Defendants**

27. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal, state and Commonwealth law. The Distributor Defendants are engaged in "wholesale distribution," as defined under federal, state and Commonwealth law. Plaintiff alleges the unlawful conduct by the Distributor Distributors is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

28. McKESSON CORPORATION ("McKesson") is a Delaware corporation with its principal place of business located in San Francisco, California, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. At all relevant times, McKesson operated as a nationwide pharmacy wholesaler. McKesson is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances at its facilities in Guayama, Puerto Rico.

29. CARDINAL HEALTH, INC. ("Cardinal"), is an Ohio corporation with its principal office in Dublin, Ohio, that at all relevant times, operated as a licensed pharmacy wholesaler in Puerto Rico.[9] Cardinal Health is licensed by the Puerto Rico Department of Health to label, repackage, and distribute prescription drugs and controlled. Cardinal's wholly-owned subsidiary Cardinal Health 120 operates a wholesale drug distribution center licensed by the Puerto Rico Department of Health to operate as a distributor of prescription drugs and controlled substances in Puerto Rico.

30. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business is in Chesterbrook, Chester County, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. At all relevant times, AmerisourceBergen operates as a nationwide pharmacy wholesaler and maintains a second wholesale drug distribution centers licensed by the Puerto Rico Department of Health to operate as a distributor of prescription drugs and controlled substances in Guayama, Puerto Rico.

31. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[10] nor the wholesale distributors[11] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

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[9] Cardinal has registered its subsidiaries for business in Puerto Rico, including Cardinal Health 120, Inc.

[10] See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[11] See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available.
Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

32. Consequently, Plaintiff has named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION & VENUE

33. This Complaint was filed as an original action in this District.

34. This voluntarily discloses the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

35. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a), because the Plaintiff is a "citizen" of the Commonwealth of Puerto Rico and the named Defendants are citizens of different states, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

36. This Court has personal jurisdiction over Defendants because they conduct business in the Commonwealth, purposefully direct or directed their actions toward the Commonwealth, some or all consented to be sued in the Commonwealth by registering an agent for service of process, they consensually submitted to the jurisdiction of the Commonwealth when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the Commonwealth necessary to constitutionally permit the Court to exercise jurisdiction.

37. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial.[12]

38. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965, because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC

39. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[13]

40. Prescription opioids have become widely prescribed. By 2010, enough

[12] See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc., 23 F. Supp. 2d 796 (1998) (citing LaSalle National Bank v. Arroyo Office Plaza, Ltd., 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); Butcher's Union Local No. 498 v. SDC Invest., Inc., 788 F.2d 535, 539 (9th Cir. 1986).

[13] See Dart, RC, et al, Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N. Eng. J. Med. 241 (2015).

prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[14]

41. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana)

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

42. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

43. Almost 5,500 people start to misuse prescription painkillers every day.[15]

44. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[16]

45. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed

[14] Katherine M. Keyes at al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).
[15] See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html
[16] See Califf et al., supra note 3.

roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[17]

46. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[18]

47. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non- medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[19]

48. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. *Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,* specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[20]

49. The societal costs of prescription drug abuse are "huge."[21]

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[17] See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf

[18] See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Today's Heroin Epidemic, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

[19] See Compton, WM, Relationship Between Nonmedical Prescription- Opioid Use and Heroin, 374 N. Eng. J. Med. 154 (2016).

[20] See Rudd, RA et al., Increases in Drug and Opioid Overdose Deaths— United States, 2000–2014, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

[21] See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., Cardinal Health, Inc. v. United States Dept. Justice, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

50. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[22]

51. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[23] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[24]

52. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[25]

53. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[26]

54. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken as candy.[27]

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[22] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010– 2015, MMWR MORB MORTAL WKLY REP. 2016;65, doi:10.15585/mmwr.mm655051e1).
[23] Opioid Crisis, NIH.
[24] Id. (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, MED CARE 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).
[25] See Rudd, RA et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).
[26] See Volkow & McLellan, supra note 2.
[27] Julie Turkewitz, 'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

55. In 2016, the President of the United States declared an opioid and heroin epidemic.[28]

56. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[29] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

57. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the National, State and Commonwealth, and l opioid epidemic.

B. Puerto Rico's Opioid Epidemic

58. The use of prescription (and non-prescription) opioids[30] is a major public health issue in the United States and in Puerto Rico, not only because of the overall high prevalence of usage but also because of the marked increases in associated morbidity, mortality[31] and the babies born addicted, diagnosed with Neonatal Abstinence Syndrome.

59. Opioids are medications that can be used to treat moderate-to-severe pain and are often prescribed following surgery, injury, or for pain related to severe health conditions such as cancer. Opioids are highly addictive medications that alone, or when combined with other drugs which depress respiration, can result in overdose and death.

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[28] See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").
[29] See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.
[30] Which includes, but is not limited, to OxyContin, Percodan, Percocet, Vicodin, Demerol.
[31] Epidemic: responding to America's prescription drug abuse crisis. Washington, DC: Office of National Drug Control Policy Executive, Office of the President of the United States, 2011 (http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf)

60. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid.[32] Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled.[33] From 2000 to 2015 more than 500,000 people died from drug overdoses.

61. Ninety-one Americans die every day from an opioid overdose.[34]

62. Prescription opioids account for approximately 70% of fatal prescription drug overdoses.[35] "In the last four or five years, the United States has seen a significant increase in deaths due to opiate overdoses," said Juan Torres Gluck, assistant administrator for treatment at the Puerto Rico Administration of Mental Health and Anti-Addiction Services (ASSMCA, by its Spanish acronym).[36]

63. In 2010, there were 148 drug induced deaths in Puerto Rico (crude rate 4.0 per 100,000 persons), which is comparable to the overall rate for Hispanic persons in the United States (5.5 per 100,000).[37] The rapid increase in prescription drug-related overdose mortality in the mainland U.S. mirrored rising trends in distribution of those drugs.[38] Limited information has been published about opioid pain reliever prescribing practices in Puerto Rico.

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[32] Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016. DOI:http://dx.doi.org/10.15585/mmwr.mm6550e1

[33] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov.

[34] CDC: Opioid Overdose: Opioid Basics: Understanding the Epidemic. https://www.cdc.gov/drugoverdose/epidemic/index.html

[35] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2013 on CDC WONDER Online Database, released 2015. 2015. Available at: http://wonder-cdc.gov/mcd-icd10.html

[36] Federal Government Will Reinforce Opioid Control. Elnuevadia.com. https://www.elnuevodia.com/english/english/nota/federalgovernmentwillreinforceopioidcontrol-2307762/

[37] Murphy S, Xu J, Kochanek K. Deaths: Final Data for 2010. National vital statistics reports; 61. Hyattsville, MD: National Center for Health Statistics. 2013. http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr6104.pdf.

[38] Paulozzi LJ, Jones CM, Mack K, Rudd R. Vital signs: overdoses of prescription opioid pain relievers - United States, 1999--2008. MMWR Morb Mort Wkly Rep. 2011;60:1487-1492.

64. The table below shows the total kilograms distributed, in Puerto Rico, between 1999 and 2013, as well as crude rates for the eight drugs included in the analyses (codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine and oxycodone). It also captures percent change between 1999 and 2013 in this distribution.

	Codeine		Fentanyl		Hydrocodone		Hydromorphone		Meperidine		Methadone		Morphine		Oxycodone	
Year	Total kg	Rate	Total kg	Rate	Total kg	Rate	Total kg	Rate	Total kg	Rate	Total kg	Rate	Total kg	Rate	Total kg	Rate
1999	56.59	.02	.20	.04	38.79	.10	.05	.00	43.53	.01	.01	.00	12.52	.03	34.39	.13
2000	na	na	.24	.05	35.82	.09	.04	.00	42.35	.01	.04	.00	9.70	.03	38.75	.15
2001	48.28	.02	.22	.04	30.55	.08	.02	.00	37.21	.01	.12	.00	8.04	.02	39.91	.16
2002	47.02	.02	.30	.06	25.09	.07	.02	.00	43.66	.01	.17	.00	7.37	.02	45.34	.18
2003	39.22	.02	.36	.07	21.87	.06	.03	.00	42.33	.01	.22	.00	8.17	.02	49.50	.19
2004	39.61	.02	.40	.08	21.76	.06	.03	.00	46.31	.01	.45	.00	7.98	.02	54.61	.21
2005	42.47	.02	.38	.07	18.96	.05	.12	.00	39.48	.01	.56	.00	8.78	.02	54.89	.21
2006	47.18	.02	.47	.09	19.68	.05	.12	.00	47.70	.01	.77	.01	10.52	.03	70.09	.27
2007	44.57	.02	.52	.10	17.36	.04	.12	.00	44.85	.01	.60	.00	10.22	.03	68.64	.26
2008	34.08	.01	.34	.06	12.29	.03	.06	.00	26.90	.01	.27	.00	10.08	.03	52.52	.20
2009	36.89	.01	.47	.09	11.70	.03	.13	.00	31.54	.01	.50	.00	11.21	.03	56.67	.21
2010	43.47	.02	.69	.14	12.55	.03	.16	.00	40.92	.01	.66	.01	14.65	.04	68.08	.27
2011	51.73	.02	.76	.16	13.12	.04	.24	.00	40.04	.01	.69	.01	14.11	.04	69.95	.28
2012	52.78	.02	na	na	12.91	.04	na	na	37.52	.01	.64	.01	na	na	67.28	.28
2013	57.20	.02	.80	.17	12.44	.03	.34	.00	38.11	.01	.48	.00	13.44	.04	68.98	.29
Percent Change 1999-2013	1.1%		293.1%		-67.9%		614.1%		-12.5%		1125.7%		7.4%		100.6%	

65. The distribution of four drugs in Puerto Rico (fentanyl, hydromorphone, methadone, oxycodone) increased over 100% between 1999 and 2013. Oxycodone distribution grew from 0.13 morphine milliequivalents (MME) kg per 10,000 persons in 1999 to .29 MMEs kilograms (kg) in 2013, a 123% increase.[39]

66. The figure below displays the rate, again in MMEs per 10,000 persons, in Puerto Rico, of kilogram distribution by year for each of the eight drugs in a line graph. Oxycodone had the highest distribution in MME kg per 10,000 persons from 2001-2013.

[39] Felix SEB, Mack Keith Altman, Jones CM. Trends in the Distribution of Opioids in Puerto Rico, 1999-2013. P R Health Sci J. 2016 Sep;35(3):165-9.
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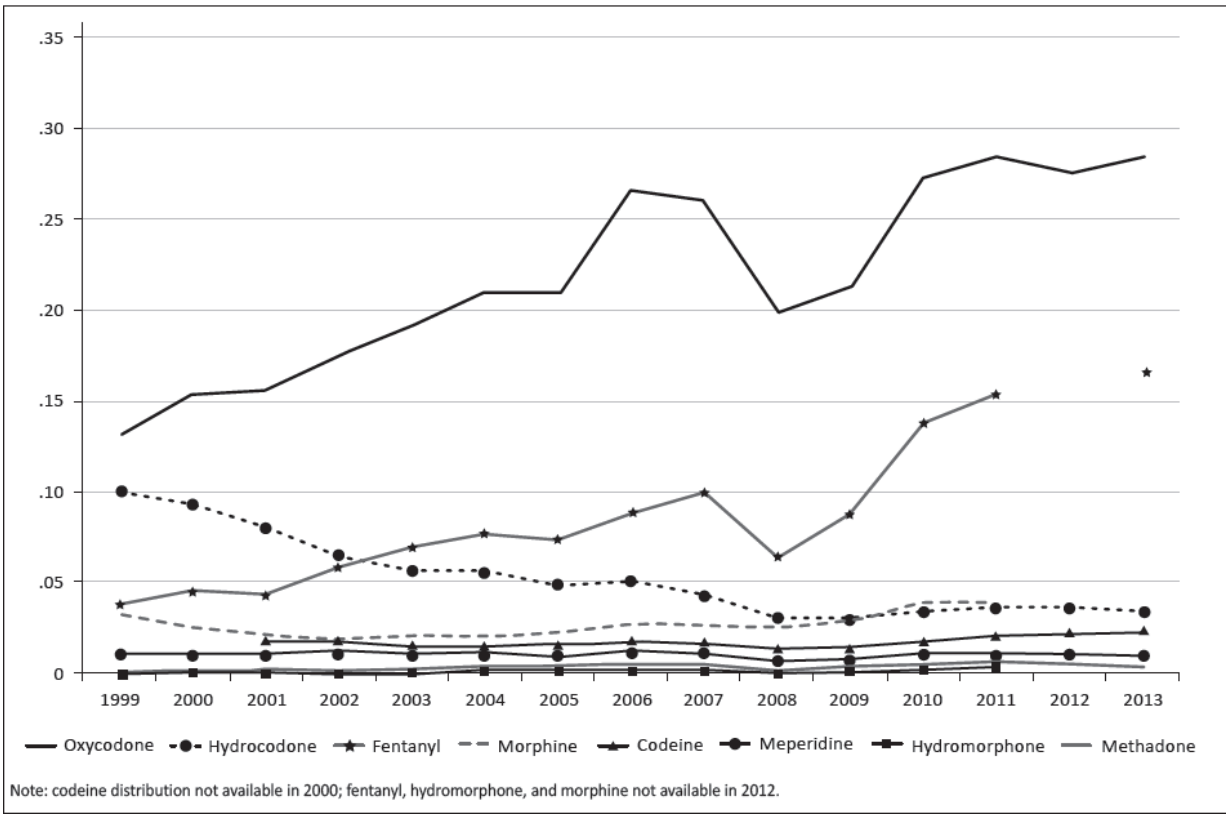
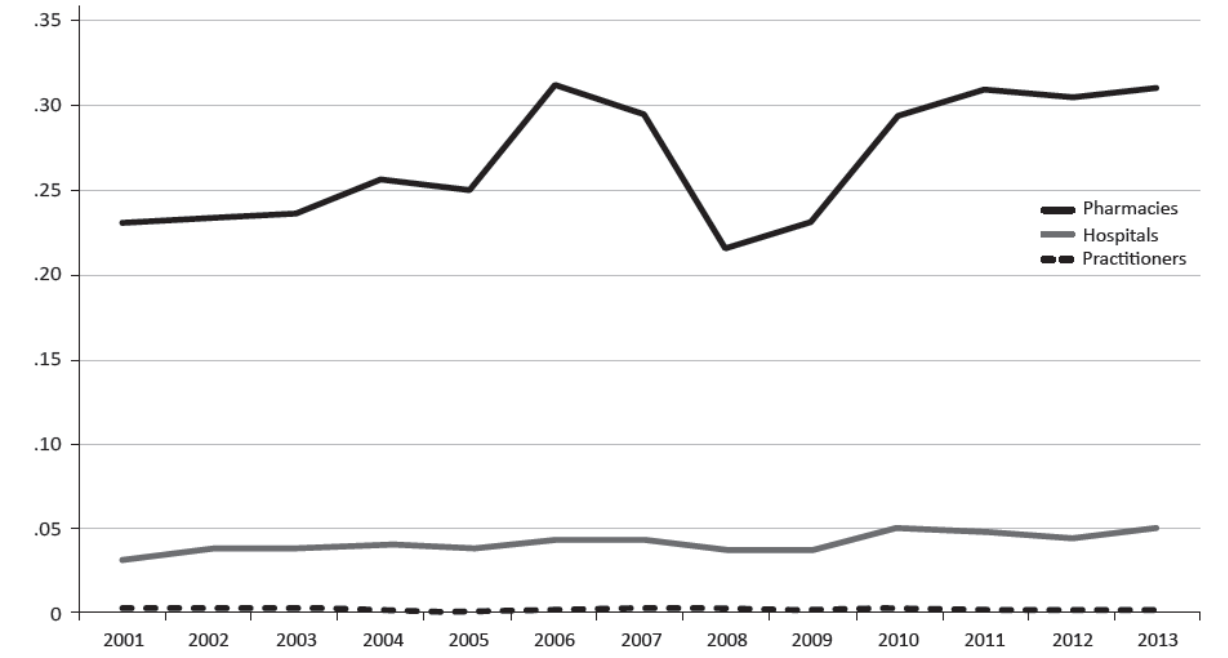


The figure below breaks down the distribution (rate in MME kg per 10,000 persons) of the eight drugs studied by entity (i.e., pharmacy, hospital and practitioner). The bulk of drugs were distributed through pharmacies. Distribution to hospitals and practitioners was relatively stable between 1999 and 2013. Distribution to pharmacies was quite variable between 2006 and 2010, but there was a substantial increase between 2001 and 2013.



*Opioids include those available in all years by entity: codeine, hydrocodone, meperidine, methadone, and oxycodone.

67. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."[40]

68. The majority of people (87.2 percent) who take prescription pain relievers do not misuse them.[41] They are taking the medications as directed: the dosage prescribed, at the

[40] U.S. Dept. Justice, DEA; Diversion Control Division. 21 C.F.R. § 1306.04(a)
[41] Hughes, A., Williams, M. R., Lipari, R. N., et al. Prescription drug use and misuse in the United States: Results from the 2015 National Survey on Drug Use and Health. NSDUH Data Review. Retrieved from Lipari RN, Williams M, Van Horn SL. Why Do Adults Misuse Prescription Drugs? The CBHSQ Report. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2013-.2017 Jul 27.

appropriate times and frequency. Nevertheless, prescription opioid use is highly associated with a risk of opioid-related death, with 1 of every 550 chronic opioid users dying within approximately 2.5 years of their first legitimate opioid prescription.[42]

69. Of the 20.5 million Americans 12 years of age or older that had a substance use disorder in 2015, 2 million had a substance use disorder involving prescription pain relievers and 591,000 had a substance use disorder involving heroin.[43]

70. In a 2013 study of opioid deaths out of Utah, of the 254 decedents, 222 (87.4 %) were identified by as having taken prescription pain medication within a year of their death. The primary source for the prescription pain medications for 92% of them was directly from a healthcare provider.[44]

71. According to national surveillance data, 914,000 people reported heroin use in 2014, a 145% increase since 2007,[45] and mortality due to heroin overdose more than quintupled, from 1,842 deaths in 2000 to 10,574 deaths in 2014.[46]

72. As a foreseeable result, rates of hospitalization due to opioid "overuse" have increased dramatically nationally from 1993 to 2012, growing from 116.7 inpatient stays per 100,000 to 295.6 inpatient stays per 100,000, a cumulative increase of 153%.[47]

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[42] Kaplovitch E, Gomes T, Camacho X, Dhalla IA, Mamdani MM, Juurlink DN. Sex differences in dose escalation and overdose death during chronic opioid therapy: a population-based cohort study. PLoS ONE. 2015; 10(8):e0134550.

[43] Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/

[44] Johnson EM, Lanier WA, Merrill RM. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J Gen Intern Med. 2013 Apr;28(4):522-9.

[45] Center for Behavioral Health Statistics and Quality. 2014 National Survey on Drug Use and Health: detailed tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

[46] CDC. Wide-ranging Online Data for Epidemiologic Research (WONDER), Multiple-Cause-of-Death file, 2000–2014. 2015 (http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf)

[47] Owens, P. L., M. L. Barrett, A. J. Weiss, et al. 2014. Hospital inpatient utilization related to opioid overuse among adults, 1993–2012 (Statistical Brief #177). http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf

73. At the same time, for every fatal opioid overdose, there are approximately 30 nonfatal overdoses.[48] These nonfatal overdoses require prompt medical treatment by first responders and emergent treatment at the hospital. Typically, the initial treatment at the scene of the overdose is the administration of naloxone or Narcan. The FDA approved a naloxone auto-injector on April 3, 2014 for adults and children, as a new therapy to treat opiate overdoses.[49] Alarmingly, even after a nonfatal overdose, opioids continue to be prescribed. For example, a 2000-2012 study[50] reported high rates of opioid prescribing for patients even after they had sustained a nonfatal opioid overdose.

74. There is also growing evidence to suggest a relationship between increased use of opioid analgesics and heroin abuse in the United States.[51] Certain consistent findings of a positive association between use of prescription opioids and heroin use are highly suggestive and plausible, given the common pharmacologic principles.[52]

75. Heroin users were 3.9 times as likely to report use of opioids in the previous year, and 2.9 times as likely to meet the criteria for abuse or dependence on opioids, as persons who did not use heroin.[53] According to the CDC, users of prescription drugs are 40 times more likely to use heroin than others, a figure that cements commonly prescribed medication as a threshold for use of more dangerous substances.

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[48] Frazier W, et al. Medication-Assisted Treatment and Opioid Use Before and After Overdose in Pennsylvania Medicaid. JAMA. 2017 Aug 22;318(8):750-752.
[49] Merlin M.A., Ariyaprakai N., and Arshad F.H.: Assessment of the safety and ease of use of the naloxone auto-injector for the reversal of opioid overdose. Open Access Emerg Med 2015; 2015: pp. 21-24
[50] Larochelle MR, Liebschutz JM, Zhang F, et al. Opioid prescribing after nonfatal overdose and association with repeated overdose: a cohort study. Ann Intern Med. 2016;164(1):1-9.
[51] Pradip et al. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the US. Center for behavioral Health Statistics and Quality Data Review. SAMHSA (2013)
http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm
[52] Compton WC, Jones CM, Baldwin GT. Relationship between Nonmedical Prescription-Opioid Use and Heroin Use.
N Engl J Med 2016; 374:154-163. January 14, 2016
[53] Becker WC, Sullivan LE, Tetrault JM, Desai RA, Fiellin DA. Non-medical use, abuse and dependence on prescription opioids among U.S. adults: psychiatric, medical and substance use correlates. Drug Alcohol Depend 2008;94:38-47

76. Anecdotal reports and localized small-scale studies have suggested that some individuals who had been abusing OxyContin® switched to heroin after the reformulation in late 2010 that made OxyContin more difficult to crush.[54]

77. One study found that use of multiple opioids was associated with transitioning to heroin.[55] Similarly, the incidence of heroin use among people who reported prior use of prescription opioids was 19 times as high as the incidence among persons who reported no previous use.[56] Additional studies involving persons from various geographic, economic, and drug-using backgrounds have shown similar associations.[57,58,59,60]

78. The 2014 National Survey on Drug Use and Health estimated that 4.3 million persons were nonmedical users of prescription pain relievers.[61] These users are 40 times more likely than the general population to use heroin or other injection.[62] Furthermore, CDC estimated a near quadrupling of heroin-related overdose deaths during 2002–2014.[63]

79. In an attempt to minimize the associated morbidity associated with injecting

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[54] Id

[55] Grau LE, Dasgupta N, Harvey AP, et al. Illicit use of opioids: is OxyContin a "gateway drug"? Am J Addict 2007;16:166-173

[56] Muhuri PK, Gfroerer JC, Davies C. Associations of nonmedical pain reliever use and initiation of heroin use in the United States. CBHSQ Data Review, 2013 (http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf).

[57] Davis WR, Johnson BD. Prescription opioid use, misuse, and diversion among street drug users in New York City. Drug Alcohol Depend 2008;92:267-276

[58] Khosla N, Juon HS, Kirk GD, Astemborski J, Mehta SH. Correlates of non-medical prescription drug use among a cohort of injection drug users in Baltimore City. Addict Behav2011;36:1282-1287

[59] Jones JD, Vosburg SK, Manubay JM, Comer SD. Oxycodone abuse in New York City: characteristics of intravenous and intranasal users. Am J Addict 2011;20:190-195

[60] Surratt HL, Inciardi JA, Kurtz SP. Prescription opioid abuse among drug-involved street-based sex workers. J Opioid Manag 2006;2:283-289

[61] Center for Behavioral Health Statistics and Quality. Behavioral health trends in the United States: results from the 2014 National Survey on Drug Use and Health. HHS publication No. SMA 15–4927. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality; 2015. https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf

[62] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010. Drug Alcohol Depend 2013;132:95–100. https://doi.org/10.1016/j.drugalcdep.2013.01.007

[63] Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in drug and opioid overdose deaths—United States, 2000–2014. MMWR Morb Mortal Wkly Rep 2016;64:1378–82. https://doi.org/10.15585/mmwr.mm6450a3

opioids, including heroin, workers from El Punto en la Montaña (The Mountain Point), brings packets of clean syringes, mounds of antibacterial wipes and rolls of gauze to addicts. Their goal is to keep opioid users - Puerto Rico has a long-running addiction crisis - free from deadly diseases they could get from injecting drugs.[64]

80. Likewise, there has been much ground lost in the struggle against viral hepatitis, including hepatitis C virus (HepC), because of the invasive spread of the opioid epidemic. State surveillance during the last 10 years reveals a nationwide increase in HCV infection among young adults.[65] The proportion of infants born to HCV infected women is also increasing nationally.[66]

81. In the U.S., more deaths are tied to hepatitis C, which can eventually cause liver cancer and failure, than the 60 other top communicable diseases combined, HIV and tuberculosis among them.[67]

82. In May 2017, the CDC released new data showing that new HepC infections have nearly tripled in the past 5 years, largely as a result of opioid-related injection drug use.[68]

> "These new infections are most frequently among young people who transition from taking prescription pills to injecting heroin, which has become cheaper and more easily available in some cases…"[I]n turn many -- most, in some communities -- people who inject drugs become infected with hepatitis C" according to the CDC's study lead author, Dr. John Ward.[69]

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[64] Miami Herald: "*People think we're the lowest:' Drug users Puerto Rico drug users get less help after the storm*". http://www.miamiherald.com/news/weather/hurricane/article180181156.html

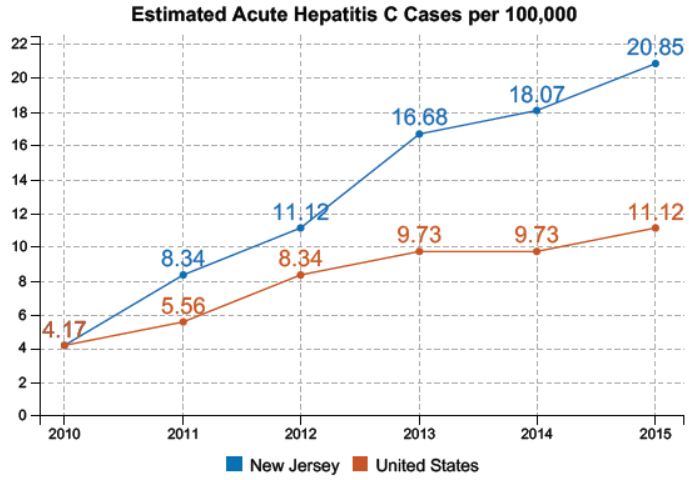
[65] Watts T et al - MMWR - 10-26-2017 - Increased Risk for Mother-to-Infant Transmission of Hepatitis C Virus Among Medicaid Recipients

[66] Watts T et al - MMWR - 10-26-2017 - Increased Risk for Mother-to-Infant Transmission of Hepatitis C Virus Among Medicaid Recipients

[67] Ly KN, Hughes EM, Jiles RB, Holmberg SD.
Rising Mortality Associated With Hepatitis C Virus in the United States, 2003–2013. Clin Infect Diseases, 15 May 201662;10:1287.

[68] https://www.cdc.gov/mmwr/volumes/66/wr/mm6618a1.htm?s_cid=mm6618a1_w

[69] Id



83. In a second CDC study, also published in May of 2017, it was reported that, between 2009 and 2014, rates of hepatitis C virus infection among US women giving birth doubled.[70] In 2014, 35 infants a day were exposed to the virus. Hepatitis C infections present when pregnant women delivered their babies increased 89% during the study period - from 1.8 to 3.4 per 1,000 live births.

84. Fueled by the increase in injection drug use ensuing from the opioid epidemic, the proportion of infants born to HCV-infected women is increasing nationwide.[71,72] Clinical signs of pediatric HCV infection often manifest slowly and can range in severity from being asymptomatic to fatal; liver transplantation is sometimes required.[73,74]

85. As the rate of HCV infection among women of childbearing age continues to increase nationally, practices for screening pregnant women for HCV and for monitoring infants born to HCV-infected mothers should be improved. Enhanced identification through testing all

[70] https://www.cdc.gov/mmwr/volumes/66/wr/mm6618a3.htm?s_cid=mm6618a3_w
[71] Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006–2012. Clin Infect Dis 2014;59:1411–9. https://doi.org/10.1093/cid/ciu643
[72] Koneru A, Nelson N, Hariri S, et al. Increased hepatitis C virus (HCV) detection in women of childbearing age and potential risk for vertical transmission—United States and Kentucky, 2011–2014. MMWR Morb Mortal Wkly Rep 2016;65:705–10. https://doi.org/10.15585/mmwr.mm6528a2
[73] Robinson JL, Doucette K. The natural history of hepatitis C virus infection acquired during childhood. Liver Int 2012;32:258–70. https://doi.org/10.1111/j.1478-3231.2011.02633.x
[74] European Paediatric Hepatitis C Virus Network. Three broad modalities in the natural history of vertically acquired hepatitis C virus infection. Clin Infect Dis 2005;41:45–51. https://doi.org/10.1086/430601

pregnant women with HCV risk factors and improved public health surveillance of infants at risk for HCV vertical transmission will improve identification, detection, and care for HCV-infected women and infants at risk for HCV vertical transmission.

86. The association between opioid and heroin usage and HIV infection was best shown on January 23, 2015, when the Indiana State Department of Health (ISDH) began an ongoing investigation of an outbreak of HIV infection, after Indiana disease intervention specialists reported 11 confirmed HIV cases traced to a rural county in southeastern Indiana.[75] Historically, fewer than five cases of HIV infection have been reported annually in this Indiana County.

87. The majority of cases were in residents of the same community and were linked to syringe-sharing partners injecting the prescription opioid oxymorphone (a powerful oral semi-synthetic opioid analgesic). As of April 21, ISDH had diagnosed HIV infection in 135 persons (129 with confirmed HIV infection and six with preliminarily positive results from rapid HIV testing that were pending confirmatory testing) in a community of 4,200 persons.[76]

88. Of the 135 persons with diagnosed HIV infection, 108 (80.0%) have reported injection drug use (IDU), four (3.0%) have reported no IDU, and 23 (17.0%) have not been interviewed to determine IDU status. Among the 108 who have reported IDU, all reported dissolving and injecting tablets of oxymorphone as their drug of choice. Some reported injecting other drugs, including methamphetamine and heroin. Coinfection with hepatitis C virus has been diagnosed in 114 (84.4%) patients.[77]

89. This HIV outbreak involves a rural population, historically at low risk for HIV, in which HIV infection spread rapidly within a large network of persons who injected prescription

[75] https://www.cdc.gov/mmWr/preview/mmwrhtml/mm6416a4.htm
[76] Id
[77] Id

opioids. The outbreak highlights the vulnerability of many rural, resource-poor populations to drug use, misuse, and addiction, in the context of a high prevalence of unaddressed comorbid conditions.[78]

90. Although overdose contributes most to drug-associated mortality, infectious complications of intravenous drug use constitute a major cause of morbidity leading to hospitalization.[79] In addition to infections from hepatitis C virus and HIV, injecting drug users are at increased risk for acquiring invasive bacterial infections, including endocarditis.[80,81] Evidence that hospitalizations for endocarditis are increasing in association with the current opioid epidemic exists[82,83,84]

91. Among patients hospitalized for drug dependence–associated endocarditis, 42% were uninsured or had Medicaid coverage, suggesting that the health care system and public payers could share a larger proportion of the cost of the increasing incidence of endocarditis, particularly if the costs of infectious complications of injection drug use, including endocarditis and HCV, continue to rise. These findings suggest a need to focus preventive interventions on harm reduction strategies such as syringe service programs, safe injection education, and treatment programs offering opioid agonist and antagonist therapies (10).

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[78] Substance Abuse and Mental Health Services Administration. Results from the 2013 national survey on drug use and health: summary of national findings. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2014. http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf

[79] Scheidegger C, Zimmerli W. Incidence and spectrum of severe medical complications among hospitalized HIV-seronegative and HIV-seropositive narcotic drug users. AIDS 1996;10:1407–14.

[80] Klevens RM, Hu DJ, Jiles R, Holmberg SD. Evolving epidemiology of hepatitis C virus in the United States. Clin Infect Dis 2012;55(Suppl 1):S3–9.

[81] Wilson LE, Thomas DL, Astemborski J, Freedman TL, Vlahov D. Prospective study of infective endocarditis among injection drug users. J Infect Dis 2002;185:1761–6.

[82] Ronan MV, Herzig SJ. Hospitalizations related to opioid abuse/dependence and associated serious infections increased sharply, 2002–12. Health Aff (Millwood) 2016;35:832–7.

[83] Wurcel AG, Anderson JE, Chui KK, et al. Increasing infectious endocarditis admissions among young people who inject drugs. Open Forum Infect Dis 2016;3:ofw157.

[84] Hartman L, Barnes E, Bachmann L, Schafer K, Lovato J, Files DC. Opiate injection-associated infective endocarditis in the southeastern United States. Am J Med Sci 2016;352:603–8.

92. There are notable increases in the use of prescription pain relievers, substance use disorder treatment admission rates, and prevalence of asthma.[85] The overall US prevalence of asthma increased from 7% of the general population in 2001 to 8% in 2010.[86] Select population demographics may have a greater prevalence in that the Black non- Hispanic population approaches 10% and the Puerto Rican subset of the Hispanic demographic has been reported at 16.5% in 2004.[87]

93. In 2008, an estimated 147,260 adults in Puerto Rico had asthma. Adult lifetime asthma prevalence was 15.2% compared with U.S. rates of 13.3%.[88] The prevalence of asthma in the U.S. is greater for women (9.2%), than men (7.0%).[89] Women are more likely to have chronic pain, be prescribed prescription pain relievers, be given higher doses, and use them for longer periods than men.[90] Further, women may become dependent on prescription pain relievers more quickly than men.[91]

94. Drug overdose is the leading cause of accidental death in the in the United States, with 47,055 such deaths in 2014, with 18,893 overdose deaths related to prescription pain relievers.[92] There is a yin-yang interaction regarding the use of opiate analgesics with asthma pathophysiology and clinical course, which may be contributing to the current epidemic of opiate analgesic deaths.

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[85] Joks R and Bluth MH. Clinical Toxicology and Its Relevance to Asthma and Atopy. Clin Lab Med, 2016-12-01, 36;4:795-801

[86] www.cdc.gov/asthma/asthmadata.htm.

[87] Id

[88] CDC's National Asthma Control Program: Asthma in Puerto Rico. https://www.cdc.gov/asthma/stateprofiles/asthma_in_pr.pdf

[89] www.cdc.gov/asthma/asthmadata.htm

[90] Center for Disease Control and Prevention : Prescription painkiller overdoses: a growing epidemic, especially among women. Atlanta (GA): Centers for Disease Control and Prevention, 2013.

[91] Id

[92] Center for Disease Control and Prevention, National Center for Health Statistics , and National Vital Statistics System, Mortality File : Number and age-adjusted rates of drug-poisoning deaths involving opioid analgesics and heroin: United States, 2000-2014. Atlanta (GA): Center for Disease Control and Prevention, 2015.

95. Taken together, both asthma and prescription pain reliever abuse are increasing.[93]

96. Heroin-dependent patients are 3 times more likely to be admitted for respiratory problems, compared with nondependent patients.[94] This relationship was more striking for those with asthma exacerbations (odds ratio of 7.0 representing a 600% increased risk). In one study, of 23 inner-city patients admitted to an inner-city intensive care unit with asthma exacerbations, 56% describe asthma exacerbations associated with heroin insufflation.[95]

97. While asthmatic patients whose asthma death is confounded by opiate use are more likely to be older, to have no immediate respiratory complaints before the event, and to be found dead[96], asthma prevalence is greater in children in general than adults (8.6% for those younger than 18 years compared with 7.4% in adults) and is greater in select populations: 13.4% in the Black non-Hispanic populations and 23.5% in the Puerto Rican subset of the Hispanic population.[97]

98. In addition, in the pediatric population (12–17 years old), the prescribing rates for prescription opioids among adolescents and young adults nearly doubled from 1994 to 2007.[98] In 2014, an estimated 28,000 adolescents in the U.S. had used heroin in the past year, and an estimated 16,000 were current heroin users. Most adolescents who misuse prescription pain relievers are given to them for free by a friend or relative; individuals often share their unused pain relievers, unaware of the dangers of nonmedical opioid use.[99] Thus, the relationship of

[93] Joks R and Bluth MH. Clinical Toxicology and Its Relevance to Asthma and Atopy. Clin Lab Med, 2016-12-01, 36;4:795-801
[94] Id
[95] Krantz A.J., Hershow R.C., Pruchand N., et al: Heroin insufflation as a trigger for patients with life-threatening asthma. Chest 2003; 123: pp. 510-517
[96] Hlavaty L., Hansma P., and Sung L.: Contribution of opiates in sudden asthma deaths. Am J Forensic Med Pathol 2015; 36: pp. 49-52
[97] www.cdc.gov/asthma/asthmadata.htm.
[98] Joks R and Bluth MH. Clinical Toxicology and Its Relevance to Asthma and Atopy. Clin Lab Med, 2016-12-01, 36;4:795-801
[99] http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

opioid use and asthma in the pediatric population may exacerbate the risks over and above the adult population.

99. Opioids are potent respiratory depressants.[100] Opioids release histamine from mast cells and opiate-induced histamine release might help to understand the development of *status asthmaticus*, a severe condition in which asthma attacks follow one another without pause, in illicit drug users.[101,102]

100. Every 25 minutes, an opioid addicted baby is born in America.[103]

101. While millions of opioid addicted adults around the nation fear and willingly avoid quitting cold-turkey because of the intense withdrawal effects, newborn babies are left without that option. They are forced to endure painful, debilitating and, at times, life-threatening opioid withdrawal symptoms.

102. The neonatal abstinence syndrome refers to a postnatal opioid withdrawal syndrome that can occur in 55 to 94% of newborns whose mothers were addicted to or treated with opioids while pregnant.[104,105]

103. NAS usually appears within 48–72 hours of birth with a constellation of clinical signs, including central nervous system irritability (e.g., tremors), gastrointestinal dysfunction (e.g., feeding difficulties), and temperature instability.[106]

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[100] Weil J.V., McCullough R.E., Kline J.S., et al: Diminished ventilator response to hypoxia and hypercapnia after morphine in normal man. N Engl J Med 1975; 292: pp. 1103-1106

[101] Levenson T., Greenberger P.A., Donoghue E.R., et al: Asthma deaths confounded by substance abuse. An Assessment of fatal asthma. Chest 1996; 110: pp. 604-610

[102] Cygan J., Trunsky M., and Corbridge T.: Inhaled heroin-induced status asthmaticus. Five Cases and a review of the literature. Chest 2000; 117: pp. 272-275

[103] National institute of Drug Abuse. Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome. https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome

[104] Finnegan LP, Connaughton JF Jr, Kron RE, Emich JP. Neonatal abstinence syndrome: assessment and management. Addict Dis 1975;2:141-158

[105] Hudak ML, Tan RC, Committee on Drugs, Committee on Fetus and Newborn. . Neonatal drug withdrawal. Pediatrics 2012;129:e540-60

[106] Hudak ML, Tan RC; Committee on Drugs; Committee on Fetus and Newborn; American Academy of Pediatrics.

104. "*It's a panicked, high-pitched wail, almost desperate, a sound you don't forget*," - Kimberly Nelson, nurse manager of the neonatal intensive care unit at the Children's National Medical Center in Washington, D.C.[107]

105. The symptoms are often worst during the first five weeks of life but can last three to six months, challenging even the most patient parents. The newborns rarely achieve deep sleep. As they endure withdrawal, they crave the darkness and calm of the womb, conditions almost impossible to replicate at home.[108]

106. The *Keeping Children and Families Safe Act*[109], passed in 2003, calls on states and the Commonwealth to protect addicted babies, regardless of whether the drugs their mothers took were illicit or prescribed. Health care providers aren't simply expected to treat the infants in the hospital. They are supposed to alert child protection authorities so that social workers can ensure the newborn's safety after the hospital sends the child home.[110]

107. But most states are ignoring the federal provisions, leaving thousands of newborns at risk every year; Reuters found that at least 36 states have laws or policies that don't require doctors to report each case.[111]

108. Infants with the neonatal abstinence syndrome are at increased risk for admission to the neonatal intensive care unit,[112,113,114] birth complications,[115] the need for pharmacologic

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Neonatal drug withdrawal. Pediatrics 2012;129:e540–60. https://doi.org/10.1542/peds.2011-3212

[107] http://www.reuters.com/investigates/special-report/baby-opioids/

[108] http://www.reuters.com/investigates/special-report/baby-opioids/

[109] https://www.congress.gov/bill/108th-congress/senate-bill/342

[110] http://www.reuters.com/investigates/special-report/baby-opioids/

[111] Id

[112] Tolia VN, Patrick SW, Bennett MM, et al. Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs. N Engl J Med 2015;372:2118-2126

[113] Uebel H, Wright IM, Burns L, et al. Reasons for rehospitalization in children who had neonatal abstinence syndrome. Pediatrics 2015;136:e811-20

[114] Cleary BJ, Donnelly JM, Strawbridge JD, et al. Methadone and perinatal outcomes: a retrospective cohort study. Am J Obstet Gynecol 2011;204:139.e1-139.e9

[115] Patrick SW, Davis MM, Lehmann CU, Lehman CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. J Perinatol 2015;35:650-655

treatment,[116,117] and a prolonged hospital stay,[118,119] outcomes that separate the mother and her infant at a critical time for infant development and bonding.[120]

109. The average length of stay for infants with the neonatal abstinence syndrome is 17 days overall and 23 days for those requiring treatment.[121]

110. Prolonged hospitalization results in the use of a greater portion of health care resources for the care of infants with the neonatal abstinence syndrome[122] than for those without the syndrome. Breast-feeding and rooming-in are promising nonpharmacologic strategies that may also improve outcomes for infants and mothers, including maternal satisfaction with and involvement in the care of the newborn.[123]

111. Physicians who specialize in NAS recognize that the condition, while often no-less than agonizing for the newborn, is treatable and needn't result in long-term harm to the child. At the same time, a diagnosis made in the first days of the baby's life should serve as a warning. It often indicates that a mother is struggling with addiction, raising questions about a family's ability to care for the infant.[124]

112. *Care for infants with NAS has placed a substantial burden on hospitals, particularly on neonatal intensive care units*. In 2012, a term infant without complications had a

[116] Tolia VN, Patrick SW, Bennett MM, et al. Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs. N Engl J Med 2015;372:2118-2126
[117] Jansson LM, Velez ML. Infants of drug-dependent mothers. Pediatr Rev 2011;32:5-12
[118] Lee J, Hulman S, Musci M Jr, Stang E. Neonatal abstinence syndrome: influence of a combined inpatient/outpatient methadone treatment regimen on the average length of stay of a Medicaid NICU population. Popul Health Manag 2015;18:392-397
[119] Wachman EM, Newby PK, Vreeland J, et al. The relationship between maternal opioid agonists and psychiatric medications on length of hospitalization for neonatal abstinence syndrome. J Addict Med 2011;5:293-299
[120] McQueen K and Murphy-Oikonen, J. Neonatal Abstinence Syndrome. (2016) N Engl J Med 2016; 375:2468-2479.
[121] Patrick SW, Davis MM, Lehmann CU, Lehman CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. J Perinatol 2015;35:650-655
[122] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA 2012;307:1934-1940
[123] McQueen K and Murphy-Oikonen, J. Neonatal Abstinence Syndrome. (2016) N Engl J Med 2016; 375:2468-2479.
[124] http://www.reuters.com/investigates/special-report/baby-opioids/

mean length of stay of 2.1 days and charge of $3,500; whereas, an infant with NAS had a mean hospital stay of 16.9 days and a mean hospital charge of $66,700.[125] Aggregate hospital charges for all infants with NAS in 2012 were estimated to be $1.5 billion; approximately 80% was financed by Medicaid programs.[126]

113. Prescription opioid overdose, abuse, and dependence carries high costs for American society. Aggregate costs for prescription opioid overdose, abuse, and dependence were estimated at over $78.5 billion (in 2013 dollars). Total spending for health care and substance abuse was over $28 billion, most of which ($26 billion) was covered by insurance.[127]

114. In nonfatal cases, costs for lost productivity - including reduced productive hours and lost production for incarcerated individuals - were estimated at about $20 billion. Nearly two-thirds of the total economic burden was due to health care, substance abuse treatment, and lost productivity for nonfatal cases. Fatal overdoses - including costs related to healthcare and lost productivity - accounted for $21.5 billion.

115. There were also $7.7 billion in criminal justice-related costs - nearly all borne directly by state, county and local governments. In addition, there were reduced tax revenues due to opioid-related productivity losses.

116. Naloxone is a life-saving drug that can revive overdose victims. Its brand name is Narcan. Naloxone (Narcan) helps restore breathing to a person who is overdosing from opioid drugs such as heroin and prescription drugs such as OxyContin, oxycodone and fentanyl. Narcan works within a minute or two and gives emergency responders time to get the person to a hospital.

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[125] Patrick SW, Davis MM, Lehmann CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. J Perinatol 2015;35:650–5. https://doi.org/10.1038/jp.2015.36

[126] Patrick SW, Davis MM, Lehmann CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. J Perinatol 2015;35:650–5. https://doi.org/10.1038/jp.2015.36

[127] Curtis S. Florence, Chao Zhou, Feijun Luo, Likang Xu. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care, 2016; 54 (10): 901

117. As a result of the epidemic of opioid abuse, and associated overdoses, most first responders now carry Narcan. However, as the result of markedly increased demand, the price of some naloxone formulations has increased by between 95% and >500% in a number of years, limiting the ability of local jurisdictions to purchase the antidote for use by paramedics and police officers.[128]

118. Costs associated with neonatal abstinence syndrome are overwhelming. Respiratory and feeding difficulties, low birth weight, and seizures are more prevalent among infants with NAS.[129] Care for infants with NAS has placed a substantial burden on hospitals, particularly on neonatal intensive care units. In 2012, a term infant without complications had a mean length of stay of 2.1 days and charge of $3,500; whereas, an infant with NAS had a mean hospital stay of 16.9 days and a mean hospital charge of $66,700.[130] Aggregate hospital charges for all infants with NAS in 2012 were estimated to be $1.5 billion; approximately 80% was financed by Medicaid programs.[131] Public health measures to prevent and treat opioid dependence before and during pregnancy are essential to reducing the incidence of NAS and its related health care burden.

C. THE MANUFACTURER DEFENDANTS' FALSE AND DECEPTIVE MARKETING OPIOIDS

119. The opioid epidemic did not happen by accident.

120. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or

[128] Gupta R, Shah ND, Ross JS. The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths. N Engl J Med 2016;375(23):2213–5
[129] Hudak ML, Tan RC; Committee on Drugs; Committee on Fetus and Newborn; American Academy of Pediatrics. Neonatal drug withdrawal. Pediatrics 2012;129:e540–60.
[130] Patrick SW, Davis MM, Lehmann CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. J Perinatol 2015;35:650–5.
[131] Id

for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

121. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

122. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

123. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

124. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[132] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[133] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non- prescription opioids, like heroin.

125. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

D. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

[132] See Katherine Eban, Oxycontin: Purdue Pharma's Painful Medicine, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful- medicine/; David Crow, Drugmakers Hooked on $10bn Opioid Habit, Fin. Times, Aug. 10, 2016, https://www. ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[133] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

126. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the Commonwealth, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the Commonwealth and Plaintiff's Community.

127. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

128. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. Direct Marketing

129. Manufacturer Defendants' direct marketing of opioids generally proceeded on

two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

130. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

131. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to- face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data

available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

132. Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimized the risks associated with Kadian and misleadingly suggested that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[134]

ii. Indirect Marketing

133. The Manufacturer Defendants' indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

134. The Manufacturer Defendants deceptively marketed opioids in the Commonwealth and Plaintiff's Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as

[134] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third- parties.

135. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

136. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

137. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants

worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

138. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

139. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that

doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

140. Defendants utilized many KOLs, including many of the same ones.

141. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, Purdue and Mallinckrodt (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

142. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very

assured that that person is not going to become addicted."[135]

143. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[136] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[137]

144. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

145. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses

[135] Good Morning America (ABC television broadcast Aug. 30, 2010).
[136] Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324 47830457817334265704460 4.
[137] Id.

146. Ironically, Dr. Webster created and promoted the Opioid Risk Tool,[138] a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

147. In. 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the Commonwealth and doctors treating members of Plaintiff's Community.[139]

148. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced

[138] https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf
[139] See Emerging Solutions in Pain, Managing Patient's Opioid Use: Balancing the Need and the Risk, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=20 9 (last visited Aug. 22, 2017).

with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[140] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[141]

149. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

150. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

151. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described

[140] Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).
[141] John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[142]

152. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the Commonwealth and Plaintiff's Community.

153. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid

[142] See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

using its line of credit.

154. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

155. Plaintiff is informed, and believes, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

156. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[143]

157. Another front group for the Manufacturer Defendants was the American Academy

[143] Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain groups/2012/05/08/ gIQA2X4qBU_ story.html.

of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

158. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon—and Mallinckrodt's then-parent, Covidien pllc—were members of the council and presented deceptive programs to doctors who attended this annual event.

159. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

160. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

161. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of

Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[144]

162. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[145] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual salesvisits.

163. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[146] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that

[144] The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).
[145] Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).
[146] Id.

drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the Commonwealth and/or Plaintiff's Community during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

164. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

E. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

165. The Manufacturer Defendants embarked upon a campaign of false and deceptive assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

166. To falsely assure physicians and patients that opioids are safe, the Manufacturer

Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that:

a. Starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed;

b. Patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs;

c. The use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and

d. Abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the Commonwealth and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

167. Some illustrative examples of the Manufacturer Defendants' false and deceptive claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid

addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[147]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com[148] (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[149]

168. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting

[147] Am. Pain Found., Treatment Options: A Guide for People Living in Pain (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[148] http://www.prescriberesponsibly.com/
[149] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter APF, Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause a true addiction."[150] Further, the book advises that even the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

169. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, Cephalon, and Mallinckrodt in the Commonwealth and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

170. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[151] The 2016 CDC Guideline further

[150] Charles E. Argoff & Bradley S. Galer, Defeat Chronic Pain Now! (2010).
[151] Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[152]

171. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[153]

172. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[154] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree

[152] Id. at 2, 25.
[153] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA- 2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.
[154] Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non- addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this Commonwealth.

173. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

174. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.[155] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[156]

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo

[155] Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2007) at 62.
[156] See Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2d ed. 2012).

appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid– the perfect recipe for addiction.

f. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

175. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

176. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false and deceptive practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to

addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

177. 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[157]

178. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline

[157] Id. at 11.

explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[158]

179. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[159] Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are advised that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."

180. A fifth category of false and deceptive statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its

[158] Id. at 26.
[159] 74 APF, Policymaker's Guide, supra note 45, at 32.

predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[160]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[161]

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[162]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"

[160] APF, Treatment Options, supra note 47, at 12.
[161] Margo McCaffery & Chris Pasero, Endo Pharm., Understanding Your Pain: Taking Oral Opioid Analgesics (Russell K Portenoy, M.D., ed., 2004).
[162] 77 APF, Policymaker's Guide, supra note 45, at 32.

challenging the correlation between opioid dosage and overdose.[163]

j. In the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are warned about of the risk of "[p]seudoaddiction [b]ecause of a [l]ow [d]ose," and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be "gradually increased to find the best daily dose, as is done with all the other oral drugs." The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

k. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[164]

181. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[165] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[166] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[167] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[168]

182. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

183. The Manufacturer Defendants made misleading claims about the ability of their

[163] The College on Problems of Drug Dependence, About the College, http://cpdd.org.
[164] Brief of APF, supra note 49, at 9.
[165] 2016 CDC Guideline, supra note 45, at 22–23.
[166] Id. at 23–24.
[167] Id. at 21.
[168] Id. at 16.

so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[169] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[170] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[171] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

F. The Manufacturer Defendants embarked upon a campaign of false and deceptive assurances grossly overstating the benefits of the opioid drugs.

184. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[172] The FDA, too, has recognized the lack of evidence to support long- term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term

[169] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.
[170] Id. at 6.
[171] Id. at 6 n.21.
[172] Id. at 15.

opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

185. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[173] This publication is still available online.

h. Endo's NIPC website "PainKnowledge.org" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project

[173] APF, Treatment Options, supra note 47.

specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[174] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[175] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

186. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

187. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[176] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the

[174] E.g., NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20I nvite.pdf.
[175] APF, Policymaker's Guide, supra note 45, at 29
[176] Letter from Thomas Abrams to Doug Boothe, supra note 32.

drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

188. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[177]

189. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience

[177] 2016 CDC Guideline, supra note 45, at 12.

toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence. Frequent, higher doses are, again, the perfect recipe for addiction.

190. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

191. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> a. OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[178]

192. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and

[178] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, Howland v. Purdue Pharma L.P., No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[179] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around- the-clock narcotic pain medication."[180]

193. Despite this, Cephalon conducted and continues to conduct a well- funded campaign to promote Actiq and Fentora for chronic pain and other non- cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non- oncologists, which promoted Actiq and Fentora for the treatment of non- cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate

[179] See U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.
[180] Id.

> (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

194. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

195. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs.

196. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[181]

[181] Harriet Ryan et al., More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

197. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

G. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

198. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this Commonwealth and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

199. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe

dosages.[182] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id*. at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

H. The Manufacturer Defendants made Materially Deceptive Statements and Concealed Materials Facts.

200. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

201. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long- term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications

[182] 2016 CDC Guideline, supra note 45, at 13.

that promoted the deceptive concept of pseudoaddiction, even for high-risk patients

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non- cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain

standards;

q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

202. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long- term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non- cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious

misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non- cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

203. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring and assisting in the distribution of patient education material that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non- cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non- cancer pain

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non- cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-

cancer pain to prescribers through in-person detailing.

204. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid- onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events

205. Defendant Actavis made and/or disseminated deceptive statements, and concealed

material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

I. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

206. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

207. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

208. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that

dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

J. The Distributor Defendants' Unlawful Distribution Of Opioids

209. Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and Puerto Rico law (*see e.g.* 24 L.P.R.A. § 2202; 24 L.P.R.A. § 2202(b)(2)(A),(C); 24 L.P.R.A. § 2203 (b); 24 L.P.R.A. § 2204 (e); 24 L.P.R.A. § 2306 (b); 24 L.P.R.A. § 2305 (a), (b); 24 L.P.R.A. § 2309; 24 L.P.R.A. § 2401 (a); 24 L.P.R.A. § 2401 (b)) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

210. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

211. Each Distributor Defendant repeatedly and purposefully breached its duties under Federal, State and Commonwealth law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's

Community.

212. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Commonwealth and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

213. The opioid epidemic in the Commonwealth of Puerto Rico, including *inter alia* in Plaintiff's Community, remains an immediate *hazard to public health and safety*.

214. The opioid epidemic in Plaintiff's Community is a temporary and continuous *public nuisance* and remains unabated.

215. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

K. Wholesale Drug Distributors Have a Duty under Federal, State and Commonwealth Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

216. Opioids are a Schedule II controlled substance under Puerto Rico law. *See* 24 L.P.R.A. § 2202. Opioids are categorized as "Schedule II" drugs because they have a "high potential for abuse" and "abuse may lead to severe psychic or physical dependence." 24 L.P.R.A. § 2202 (b)(2)(A),(C); 21 U.S.C. § 812(b)(2)(A),(C).

217. As wholesale drug distributors, each Defendant was required under Puerto Rico law to be licensed by the Puerto Rico Department of Health. 24 L.P.R.A. § 2202 (a). To receive and maintain this license, each of the Defendant Wholesale Distributors assumed a duty to comply with all applicable federal, state and Commonwealth laws and regulations and all

applicable DEA, State, Commonwealth and local regulations. 24 L.P.R.A. § 2203 (b).

218. The Puerto Rico Department of Health may revoke, suspend, limit or refuse to issue a license to a distributor for engaging in conduct which is harmful to the public health, safety or welfare. 24 L.P.R.A. § 2204 (e).

219. Each Defendant was also required to be registered with the Puerto Rico Secretary of Health. 24 L.P.R.A. § 2202 (a); 24 L.P.R.A. § 2203 (b).

220. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutoryscheme.

221. Each Distributor Defendant has an affirmative duty under federal and Puerto Rico law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). Puerto Rico law requires that Distributors and others maintaining stocks or having controlled substances in production areas or on hand for distribution shall provide effective controls and procedures to guard against theft and diversion of the substances. 24 L.P.R.A. § 2309

222. Puerto Rico law also requires Distributors to ensure that prescription drugs are distributed only for lawful purposes. Licensed distributors must follow written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts. *See* 24

L.P.R.A. § 2309.

223. The Puerto Rico Controlled Substance Act prohibits the manufacture, delivery, or possession with intent to manufacture or deliver, a controlled substance by a person not registered under the Act, or a practitioner not registered or licensed by the appropriate Commonwealth board. *See* 24 L.P.R.A. § 2401 (a).Violation of this provision as to a Schedule II narcotic is a felony. 24 L.P.R.A. § 2401 (b).

224. The Act also prohibits the dissemination or publication of any false or materially misleading advertisement. *See* 24 L.P.R.A. § 2305 (a). Puerto Rico law further prohibits the furnishing of false or fraudulent material information in, or omission of any material information from any application, report, or other document required to be kept or filed under the Act, or any record required to be kept by the Act. *See* 24 L.P.R.A. § 2306 (b); 24 L.P.R.A. § 2305 (a), (b).

225. Puerto Rico has declared that Puerto Rico consumers of prescription drugs will be better assured of safe and effective prescription drug products if the Commonwealth joins with other jurisdictions to require the licensure of all persons who operate facilities from which they engage in the wholesale distribution of prescription drugs. Further, the legislature has declared that it is the further intent of the General Assembly to promote the safety and effectiveness of prescription drug products by requiring all persons who operate facilities within this Commonwealth from which they engage in the wholesale distribution of prescription drugs to secure a license and meet minimum quality assurance and operational standards as required by the Act.

226. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the

Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

227. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

228. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[183] Regardless, all flagged orders must be reported. *Id.*

229. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified

[183] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

approach to narcotic and dangerous drug control.[184]

230. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[185]

231. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[186]

232. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[187]

233. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when

[184] See 1970 U.S.C.C.A.N. 4566, 4571-72.

[185] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, Masters Pharm., Inc. v. U.S. Drug Enf't Admin. (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, About, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, Mission, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

[186] See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[187] See Brief for HDMA and NACDS, supra note 81, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[188]

234. The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[189] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[190]

235. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[191] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[192]

236. The letter further explains:

a. The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

b. The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the

[188] Rannazzisi Letter, supra note 82, at 2.
[189] Id. at 1.
[190] Id. at 2.
[191] See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.
[192] Id.

order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

c. Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

d. When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

e. Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[193]

f. Finally, the DEA letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[194]

237. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but

[193] Id.
[194] Id.

undertake such efforts as responsible members of society."[195]

238. Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[196]

239. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

240. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

241. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

242. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

[195] See Brief of HDMA, supra note 21, 2012 WL 1637016, at *2.
[196] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

243. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the Commonwealth and Plaintiff's Community.

244. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

245. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

i. The Distributor Defendants Breached their Duties

246. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[197]

247. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[198]

248. The Distributor Defendants failed to report "suspicious orders" originating from

[197] See Rannazzisi Decl. ¶ 10, filed in Cardinal Health, Inc. v. Holder, No. 1:12- cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.
[198] Masters Pharmaceuticals, Inc., 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal, state and Commonwealth authorities, including the DEA and/or the Commonwealth Board of Pharmacy.

249. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

250. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

251. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

252. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal, state and Commonwealth law.

253. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[199]

254. The federal, state and Commonwealth laws at issue here are public safety laws.

255. The Distributor Defendants supplied prescription opioids to obviously suspicious

[199] See Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

256. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal, state and Commonwealth law which are required to legally acquire and maintain a license to distribute prescription opiates.

257. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

258. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

ii. The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties

259. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal, state and Commonwealth law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

260. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of

wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[200]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[201]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[202]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[203]

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[204]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[205]

261. The position taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of

[200] Brief for HDMA and NACDS, supra note 81, 2016 WL 1321983, at *4–5.
[201] Id. at *8 (citations and quotation marks omitted).
[202] Id. at *14.
[203] Id. at *22.
[204] Id. at *24–25.
[205] Id. at 26.

the dangerous drugs.[206]

262. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting.[207] The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."[208]. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders.[209] A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

263. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the

[206] See Brief of HDMA, supra note 21, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").
[207] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).
[208] Id. at 212.
[209] *Id.* at 218–19, 226.

DEA Letters."[210]

264. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[211] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers" including the McKesson Distribution Center located in "Washington Courthouse, Ohio."[212] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.[213]

265. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[214] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[215] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report

[210] See Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.
[211] Id. at 4.
[212] Id.
[213] Id. at 6.
[214] Id. at 4.
[215] Id.

suspicious orders to DEA, in accordance with McKesson's obligations."[216] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[217]

266. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

267. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[218] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[219] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution

[216] Id.; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.
[217] See 2017 Settlement Agreement and Release, supra note 109, at 6.
[218] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[219] Id.

Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and

> report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

268. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[220]

269. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

270. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal

[220] See Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e- 7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation- of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9- a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership- in-wv-amid-flood-of-pain-pills-.

activity."[221] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

271. Similarly, Defendant McKesson publicly stated that it has a "best-in- class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[222] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

272. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

273. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, Commonwealth, and in Plaintiff's Community.

274. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

275. The wrongful actions and omissions of the Distributor Defendants which have

[221] Lenny Bernstein et al., How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for- patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their- job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[222] Scott Higham et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527- 949c5893595e_story.html.

caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

276. The Distributor Defendants have abandoned their duties imposed under federal state and Commonwealth law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the Commonwealth and Plaintiff's Community.

L. The Manufacturer Defendants' Unlawful Failure To Prevent Diversion And Monitor, Report, And Prevent Suspicious Orders.

277. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and Puerto Rico law

278. The Manufacturing Defendants were required to comply with the same licensing and permitting requirements as the Distributor Defendants.

279. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

a. maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . .[223]

b. Additionally, as "registrants" under Section 823, the Manufacturer Defendants

[223] 21 USCA § 823(a)(1) (emphasis added).

were also required to monitor, report, and prevent suspicious orders of controlled substances:

> c. The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[224]

280. Like the Distributor Defendants, the Manufacture Defendants breached these duties.

281. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

282. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of

[224] 21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)."

controlled substances" and to maintain "effective controls against diversion."[225]

283. Similarly, Puerto Rico law requires that Distributors and others "maintaining stocks or having controlled substances in production areas or on hand for distribution shall provide effective controls and procedures to guard against theft and diversion of the substances."

284. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[226]

285. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street . . . . "Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[227]

286. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied

[225] 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).
[226] See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million- settlement-failure-report-suspicious-orders
[227] Id.

various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[228]

287. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[229]

288. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

289. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C,F.R. § 1301.74(b).

290. The above includes, but is not limited to Mallinckrodt's alleged failure to:

a. conduct adequate due diligence of its customers;

b. detect and report to the DEA orders of unusual size and frequency

c. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

d. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

e. orders that purchased a disproportionate amount of a substance which is most

[228] Id.
[229] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao- edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

often abused compared to other products, and

f. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

g. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[230]

291. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[231]

292. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[232]

293. The same duties imposed by federal law on Mallinckrodt were imposed upon all

[230] 2017 Mallinckrodt MOA at p. 2-3.
[231] Id. at 3-4.
[232] Id. at p.5.

Manufacturer Defendants.

294. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

295. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

296. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

297. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

298. The Manufacturer Defendants have misrepresented their compliance with federal law.

299. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

300. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

301. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the

unlawful diversion of opioids into Plaintiff's Community.

M. Defendants' Unlawful Conduct And Breaches Of Legal Duties Caused The Harm Alleged Herein And Substantial Damages.

302. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the Commonwealth and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic

303. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[233]

304. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[234]

305. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[235]

306. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[236]

307. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opiates.

[233] See Dart et al., supra note 13.
[234] See Volkow & McLellan, supra note 2.
[235] See Califf et al., supra note 3.
[236] See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., supra note 13.

308. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's Community and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

309. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Commonwealth and in Plaintiff's Community.

310. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Commonwealth and in Plaintiff's Community.

311. Defendants repeatedly and purposefully breached their duties under Federal, State and Commonwealth law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

312. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Commonwealth and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff and Plaintiff's Community.

313. Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

314. Plaintiff seeks economic damages from the Defendants as reimbursement for the

costs association with past efforts to eliminate the hazards to public health and safety.

315. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

316. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[237]A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[238]

317. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[239]

318. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

V. STATUTES OF LIMITATIONS DO NOT BAR THE MUNICIPALITY'S CLAIMS.

A. Enforcement of Public Right

319. No statute of limitation can be pleaded against the Plaintiff, which seeks to enforce strictly public rights.

B. Equitable Estoppel

320. To the extent any statute of limitations defense would apply, Defendants are

[237] See Rudd et al., supra note 20, at 1145.
[238] See Johns Hopkins Bloomberg School of Public Health, The Prescription Opioid Epidemic: An Evidence-Based Approach (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety- and-effectiveness/research/prescription- opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.
[239] See Office of Nat'l Drug Control Policy, Exec. Office of the President, Epidemic: Responding to America's Prescription Drug Abuse Crisis (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

equitably estopped from relying upon such a defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the Commonwealth, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the Commonwealth and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the Commonwealth, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

321. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[240]

322. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[241]

323. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[242]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require

[240] Bernstein et al., supra note 113.
[241] Higham et al., supra note 114.
[242] Brief for HDMA and NACDS, supra note 81, 2016 WL 1321983, at *3-4, *25.

distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

324. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

325. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities.

326. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the Commonwealth, and

Plaintiff's Community were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the Commonwealth and in Plaintiff's Community.

327. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

328. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

C. Fraudulent Concealment.

329. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

330. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

331. In light of their statements to the media, in legal filings, and settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

332. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

VI. LEGAL CAUSES OF ACTION

COUNT I. PUBLIC NUISANCE (Against all Defendants)

333. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

334. Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts § 821B.

335. Puerto Rico has declared that Puerto Rico consumers of prescription drugs will be better assured of safe and effective prescription drug products if the Commonwealth joins with other jurisdictions to require the licensure of all persons who operate facilities from which they engage in the wholesale distribution of prescription drugs. Further, the legislature has declared that it is the further intent of the General Assembly to promote the safety and effectiveness of prescription drug products by requiring all persons who operate facilities within this Commonwealth from which they engage in the wholesale distribution of prescription drugs to secure a license and meet minimum quality assurance and operational standards as required by the Act.

336. By causing dangerously addictive drugs to flood the community, and to be

diverted for illicit purposes, in contravention of federal, State and Commonwealth law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff's Community to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

337. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a continuing course of conduct that injuriously affects the safety, health, and morals of the people of the Plaintiff's Community.

338. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of the Commonwealth and Plaintiff's Community.

339. Plaintiff alleges that Defendants wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

340. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

341. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

342. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will

be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff's Community.

343. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

344. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

345. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

346. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally Plaintiff's Community is of a continuing nature.

347. Defendants' actions have been of a persistent and continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

348. A violation of any rule or law controlling the distribution of a drug of abuse in

Plaintiff's Community and the Commonwealth is a public nuisance.

349. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

350. Defendants' ongoing and repeated course of conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

351. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

352. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

353. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

354. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law.[243]

355. Defendants' conduct in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, will likely be diverted for non-

[243] *See*, e.g., 21 U.S.C. § 812 (b)(2).

legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

356. It is, or should be, reasonably foreseeable to defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

357. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

358. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

359. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

360. The presence of diverted prescription opioids in Plaintiff's Community, and the consequence of prescription opioids having been diverted in Plaintiff's Community, proximately results in and/or substantially contributing to the creation of significant costs to the Plaintiff and

to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

361. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

362. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community, costs borne by Plaintiff's Community and the Plaintiff, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

363. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

364. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and

failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

365. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiff's Community.

366. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

367. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

368. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

369. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual ongoing injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

370. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

371. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

372. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

373. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

374. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal, state and Commonwealth law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

375. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties,

and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to the following:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers.

c. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts

d. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

e. The opioid epidemic has increased health care costs

f. Employers have lost the value of productive and healthy employees.

g. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

h. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

i. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

j. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Community.

k. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the

harm inflicted by Defendants' actions.

l. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint.

m. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

n. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II. RACKETEER INFLUENCED AND CORRUPT

ORGANIZATIONS ACT 18 U.S.C. 1961, *et seq.* (Against All Defendants)

376. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows

377. Plaintiff brings this Count on behalf of itself against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

378. Each Defendant is associated with an enterprise which affects interstate commerce for purposes which include the illegal distribution of opioids. As explained herein, each Defendant conducted or participated in the enterprise's affairs through commission of criminal offenses which constitute a pattern of racketeering activity.

379. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in- fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest

in property."

380. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt."[244]

381. Defendant corporations are "persons" within the meaning of 18 U.S.C.A. § 1961(3) which conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C.A. § 1962.[245]

382. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity."[246] The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'"[247] The second category is not a more generalized description of the first. *Id*

383. The Plaintiff was injured in its business or property as a result of each Defendant's wrongful conduct and is a "person" who can bring an action for violation of section 1962, as that term is defined in 18 U.S.C.A. § 1961(3). "Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and

[244] 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).
[245] *Accord In re ClassicStar Mare Lease Litig.*, 727 F.3d at 490- 494 (6th Cir. 2013).
[246] 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009).
[247] *Turkette*, 452 U.S. at 577.

the cost of the suit, including a reasonable attorney's fee...."[248]

384. Each Defendant conducted and participated in the conduct of the affairs of each Defendant's Opioids Marketing Enterprise through a pattern of racketeering activity, which violates 18 U.S.C.A. § 1962(c).

385. Regardless of any licenses or registrations held by Defendants to distribute dangerous and harmful drugs, their conduct was not "lawful." Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

386. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.*(the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

387. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like

[248] 18 U.S.C.A. § 1964. *See Plaintiff of Oakland v. City of Detroit,* 866 F.2d 839 (6th Cir. 1989) (Plaintiff was "person" with standing to bring a RICO claim), *cert. den.*, 497 U.S. 1003 (1990)).

opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[249]

388. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[250] As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[251] In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

389. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and

[249] 1970 U.S.C.C.A.N. 4566 at 5490; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/ files/Rannazzisi%20Testimony_0.pdf).
[250] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).
[251] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

390. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[252] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. §1961(4) because it is a corporation and a legal entity.

391. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

392. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as

[252] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/ about/hda-history.

a RICO enterprise.

393. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

A. THE OPIOID DIVERSION ENTERPRISE

394. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[253] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[254] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[255] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[256] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[257] Moreover, the closed-system

[253] Joseph T. Rannazzisi Decl. ¶ 4, Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).
[254] See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
[255] Gonzalez v. Raich, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).
[256] See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).
[257] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0. pdf).

was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[258] All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[259] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[260] The result is the scourge of addiction that has occurred.

395. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[261] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[262]

396. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[263] When

[258] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).
[259] Id.
[260] Joseph T. Rannazzisi Decl. ¶ 10, Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).
[261] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).
[262] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).
[263] 1970 U.S.C.C.A.N. 4566 at 5490; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[264]

397. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[265]

398. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

399. The opioid epidemic has its origins in the mid-1990s when, between 1997 and

[264] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0. pdf).
[265] Id. (citing 21 U.S.C. 842(b)).

2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[266] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[267]

400. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

401. At all relevant times, the Opioid Diversion Enterprise:

a. had an existence separate and distinct from each RICO Defendant;

b. was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged;

c. was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants;

d. characterized by interpersonal relationships among the RICO Defendants;

e. had sufficient longevity for the enterprise to pursue its purpose; and

f. functioned as a continuing unit.[268]

402. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid

[266] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural- urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.
[267] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic.
[268] *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009).

Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

403. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.[269] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

404. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating Federal, State and Commonwealth laws requiring the maintenance of effective controls against diversion of prescription opioids, and the

[269] See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed- enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e- 7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation- of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9- a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership- in-wv-amid-flood-of-pain-pills-.

identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

405. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the Municipality and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

406. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

407. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a

separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

408. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

409. The Pain Care Forum ("PCF") has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal, state and Commonwealth policies regarding the use of prescription opioids for more than a decade.

410. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[270] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[271]

411. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[272] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen

[270] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic (emphasis added).
[271] Id.
[272] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM- Meetings-Schedule-amp.pdf.

Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).[273] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[274] Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

412. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

413. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

414. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the

[273] Id. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[274] Id. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/ about/executive-committee.

Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[275] And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

415. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[276] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

416. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[277] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current

[275] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/ manufacturer.
[276] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/ pdfs/membership/manufacturer-membership-benefits.ashx?la=en.
[277] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/ media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[278]

417. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[279]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e- commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.[280]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[281]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[282]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[283]

[278] Id.
[279] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and- committees
[280] Id.
[281] Id.
[282] Id.
[283] Id.

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[284]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[285]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[286]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[287]

j. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

418. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[288] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[289] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high- level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring

[284] Id.
[285] Id.
[286] Id.
[287] Id.
[288] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.
[289] Id.

these events.[290]

419. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

420. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[291] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[292] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[293] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

421. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and

[290] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management- conference.
[291] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; see also, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation- letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation- letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.
[292] Id.
[293] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

422. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

423. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[294] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital

[294] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic.

and in all 50 statehouses on issues including opioid-related measures.[295] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[296]

424. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

425. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal State and Commonwealth obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

426. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

427. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

428. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or

[295] Id.
[296] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

diversion of their prescription opioids.

429. Defendants paid nearly $800 million dollars to influence federal, state, and Commonwealth governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

430. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

431. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[297]

432. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor

[297] See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare- distribution-alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed- enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e- 7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation- of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9- a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership- in-wv-amid-flood-of-pain-pills-.

Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

433. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

434. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[298] On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non- controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

435. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[299] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to

[298] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[299] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[300]

436. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the Federal, State and Commonwealth Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

437. The RICO Defendants worked together to control the flow of information and influence Federal, State and Commonwealth governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

438. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

[300] Id.

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[301]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

439. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY

440. The RICO Defendants conducted and participated in the conduct of the Opioid

[301] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

i. The RICO Defendants Engaged in Mail and Wire Fraud.

441. he RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal, state and Commonwealth regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

442. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

443. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their

compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

444. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

445. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

446. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

447. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

448. Purdue manufactures multiple forms of prescription opioids, including but not

limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

449. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

450. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

451. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

452. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

453. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction

454. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

455. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

456. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the

Distributor Defendants in this jurisdiction.

457. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

458. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

459. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

460. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal State and Commonwealth laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

461. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all Federal, State and Commonwealth regulations regarding the identification and reporting of suspicious orders of prescription opioids.

462. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

463. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

464. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their Federal, State and Commonwealth obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

465. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

466. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

467. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

468. The RICO Defendants hid from the general public, and suppressed and/or ignored

warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

469. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

470. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

471. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

472. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

473. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

474. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

475. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

476. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

477. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

478. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

479. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

ii. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.

480. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

481. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.[302]

482. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances., and inform the DEA of suspicious orders when

[302] 21 U.S.C. § 483(d)(1).

discovered by the registrant.[303]

483. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

484. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

485. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay

486. $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[304]

487. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware

[303] 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).
[304] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017(), http://www.mckesson.com/about-mckesson/newsroom/press- releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past- claims/.

of a pill mill operating out of Los Angeles yet failed to alert the DEA.[305] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[306] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[307]

488. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[308] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[309]

489. Plaintiff is informed and believes that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their

[305] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[306] Id.
[307] Id.
[308] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[309] Id.

mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[310] For example:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled

[310] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

490. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

491. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

492. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

493. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

494. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the distribution of dangerous and harmful drugs to persons, including minors, in violation of federal law, 21 CFR 1301.74(b) at retail pharmacies, hospitals, and other health care facilities throughout Puerto Rico.

495. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including thousands of separate instances of use of the United States Mail or interstate wire facilities in furtherance of each Defendant's unlawful Opioids Diversion Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity. Each Defendant specifically intended to obtain money by means of false pretenses, representations, and promises, and used the mail and interstate wires for the purpose of executing this scheme; specifically, each Defendant communicated with its respective retail pharmacy customers via wire and used the mail to

receive orders and sell drugs unlawfully. Any violation of the mail or wire fraud statutes is defined as "racketeering activity."[311]

496. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

497. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market

498. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

499. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and its citizens to be injured in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

500. Plaintiff's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

501. Plaintiff's injuries and those of her citizens were directly caused by the RICO Defendants' racketeering activities.

502. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

[311] 18 U.S.C.A. § 1961(1)(B).

503. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, a civil penalty of up to one hundred thousand dollars, forfeiture as deemed proper by the Court, attorney fees and costs[312] and expenses of suit and pre- and post-judgment interest.

COUNT III. RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO) 18 U.S.C. 1962(d), *et seq.* (Against All Defendants)

504. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows

505. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions.[313]

506. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE

507. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Opioid Diversion

[312] 18 U.S.C.A. §1964(c)
[313] 18 U.S.C. § 1962(d).

Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

508. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY

509. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES

510. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

511. Plaintiff's injuries, and those of her citizens, were proximately caused by the RICO Defendants' conspiracy to violate Section 1962(c). But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug- addicted residents.

512. Plaintiff's injuries and those of her citizens were directly caused by the RICO Defendants' conspiracy to violate Section 1962(c).

513. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

514. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia

actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT IV. FRAUD AND FRAUDULENT MISREPRESENTATION (Against All Defendants)

515. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

516. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information which made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

517. As alleged herein, Defendants made false statements regarding their compliance with Federal, State and Commonwealth law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

518. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

519. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, and persons on whom Plaintiff relied.

520. These false representations and concealments were reasonably calculated to

deceive Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids for persons in Plaintiff's Community, were made with the intent to deceive these persons, Plaintiff and Plaintiff's Community to rely on these false representation and concealments and act accordingly, and did in fact deceive these persons, Plaintiff, and Plaintiff's Community.

521. Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

522. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

523. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

524. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

525. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT V. UNJUST ENRICHMENT (Against All Defendants)

526. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

527. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the Plaintiff and its residents.

528. As an expected and intended result of their conscious wrongdoing as set forth in

this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

529. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

530. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of Plaintiff.

531. In equity and good conscience, it would be unjust and inequitable to permit defendants to enrich themselves at the expense of the Plaintiff and its residents.

532. By reason of the foregoing, Defendants must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiff.

COUNT VI. NEGLIGENCE (Against All Defendants)

533. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein

534. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids.

535. Distributor Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

536. As a proximate result, Distributor Defendants and its agents have caused Municipality of Guayama to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the Municipality has borne the massive costs of these

illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for the Municipality Residents and using the Municipality's resources in relation to opioid use and abuse.

537. Distributor Defendants were negligent in failing to monitor and guard against third- party misconduct and participated and enabled such misconduct.

538. Distributor Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

539. Distributor Defendants are in a class of a limited number of parties that can legally distribute opioids, which places it in a position of great trust by the Municipality.

540. he trust placed in Distributor Defendants by Guayama through the license to distribute opioids in Guayama creates a duty on behalf of Distributor Defendants to prevent diversion of the medications it supplies to illegal purposes.

541. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the Municipality and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

542. Distributor Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

543. Distributor Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

544. Distributor Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

545. Distributor Defendants are in exclusive control of the management of the opioids it distributed to pharmacies and drug stores in Guayama.

546. Guayama is without fault and the injuries to the Municipality and its residents would not have occurred in the ordinary course of events had Distributor Defendants used due care commensurate to the dangers involved in the distribution of opioids.

PUNITIVE DAMAGES

547. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

548. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression, and/or malice, and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal, state and Commonwealth statutes, and common law.

549. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Commonwealth and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of

the community, and an award of punitive damages is appropriate, as punishment and deterrence.

550. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence, and exhibited an entire want of care that would raise the presumption of a conscious reckless indifference to consequences.

RELIEF

551. WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

552. Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants;

553. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unlawful sales of prescription opioid pills and ordering temporary, preliminary or permanent injunction;

554. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

555. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

556. Awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

557. Awarding the Plaintiff the damages caused by the opioid epidemic, including

a. costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related

addiction or disease, including overdoses and deaths;

b. costs for providing treatment, counseling, and rehabilitation services;

c. costs for providing treatment of infants born with opioid-related medical conditions;

d. costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and

e. costs associated with law enforcement and public safety relating to the opioid epidemic.

558. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

559. Granting the Plaintiff

a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

b. Pre-judgment and post-judgment interest; and,

c. All other relief as provided by law and/or as the Court deems appropriate and just.

Respectfully submitted,

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